

Robert Greene Sterne
Edward J. Kessler
Jorge A. Goldstein
David K.S. Cornwell
Robert W. Esmond
Tracy-Gene G. Durkin
Michele A. Cimbala
Michael B. Ray
Robert E. Sokohl
Eric K. Steffe
Michael Q. Lee
Steven R. Ludwig
John M. Covert
Linda E. Alcorn
Robert C. Millonig
Lawrence B. Bugaisky
Donald J. Featherstone
Michael V. Messinger

Judith U. Kim
Timothy J. Shea, Jr.
Patrick E. Garrett
Heidi L. Kraus
Edward W. Yee
Albert L. Ferro*
Donald R. Banowitz
Peter A. Jackman
Molly A. McCall
Teresa U. Medler
Jeffrey S. Weaver
Kendrick P. Patterson
Vincent L. Capuano
Eldora Ellison Floyd
Thomas C. Fiala
Brian J. Del Buono
Virgil Lee Beaston*
Kimberly N. Reddick

Theodore A. Wood
Elizabeth J. Haanes
Bruce E. Chalker
Joseph S. Ostroff
Frank R. Cottingham
Christine M. Lhulier
Rae Lynn Prengaman
Jane Shershenovich*
Lawrence J. Carroll*
George S. Bardmesser
Daniel A. Klein*
Rodney G. Maze
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Michael D. Specht
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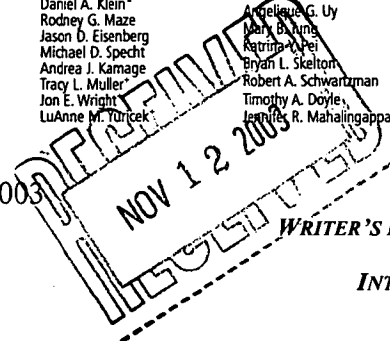
John J. Figueroa
Ann E. Summerfield
Registered Patent Agents*
Karen R. Markowicz
Nancy J. Leith
Helene C. Carlson
Gaby L. Longworth
Matthew J. Dowd
Aaron L. Schwartz
Angelique G. Uy
Mary B. Bunn
Kathleen A. Per
Bryan L. Skelton
Robert A. Schwartzman
Timothy A. Doyle
Jennifer R. Mahalingappa

Teresa A. Colella
Jeffrey S. Lundgren
Victoria S. Rutherford
Eric D. Hayes

Of Counsel
Kenneth C. Bass III
Evan R. Smith

*Admitted only in Maryland
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Federal Agencies

November 6, 2003



Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Group Art Unit 1645
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Technology Center 2600

Re: U.S. Utility Patent Application
Appl. No. 09/839,565; Filed: October 17, 2001
For: **PTH Receptor and Screening Assay Utilizing the Same**
Inventors: Gardella *et al.*
Our Ref: 0609.4730000/LBB/M-G

Sir:

Transmitted herewith for appropriate action are the following documents:

1. First Supplemental Information Disclosure Statement;
2. Form PTO-1449 (10 pages);
3. Copies of thirty-one (31) cited documents; and
4. One (1) return postcard.

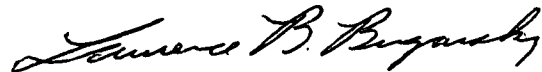
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
November 6, 2003
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Lawrence B. Bugaisky
Attorney for Applicants
Registration No. 35,086

Enclosures

SKGF_DC1:196590.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gardella *et al.*

Appl. No. 09/869,565

Filed: October 17, 2001

For: **PTH Receptor and Screening
Assay Utilizing the Same**

Confirmation No. 4604

Art Unit: 1645

Examiner: *To Be Assigned*

Atty. Docket: 0609.4730600/TBB/M-G

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First Supplemental Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed on May 9, 2003, in connection with the above-captioned application. A copy of each document is also provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

This First Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Lawrence B. Bugaisky
Attorney for Applicants
Registration No. 35,086

Date: November 6, 2003

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

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FORM PTO-1449

**FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT**ATTY. DOCKET NO.
0609.4730000/LBB/M-GAPPLICATION NO.
09/869,565APPLICANT
Gardella et al.FILING DATE
October 17, 2001GROUP
1645**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP4	WO 92/01810	02/06/1992	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>28</u>	Bergwitz, C., et al., "Identification, Functional Characterization, and Developmental Expression of Two Nonallelic Parathyroid Hormone (PTH)/PTH-Related Peptide Receptor Isoforms in <i>Xenopus laevis</i> (Daudin)," <i>Endocrinol.</i> 139:723-732, The Endocrine Society (February 1998)
	AS	<u>28</u>	Bettoun, J.D., et al., "Cloning and Characterization of the Promoter Regions of the Human Parathyroid Hormone (PTH)/PTH-Related Peptide Receptor Gene: Analysis of Deoxyribonucleic Acid from Normal Subjects and Patients with Pseudohypoparathyroidism Type 1b," <i>J. Clin. Endocrinol. Metab.</i> 82:1031-1040, The Endocrine Society (April 1997)
	AT	<u>28</u>	Bettoun, J.D., et al., "Developmental Upregulation of Human Parathyroid Hormone (PTH)/PTH-related Peptide Receptor Gene Expression from Conserved and Human-specific Promoters," <i>J. Clin. Invest.</i> 102:958-967, The American Society for Clinical Investigation, Inc. (September 1998)

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	AL						Yes No
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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	29	Broadus, A.E., and Stewart, A.F., "Parathyroid Hormone-Related Protein, Structure, Processing, and Physiological Actions," in <i>The Parathyroids</i> , Bilezikian, J.P., ed., Raven Press, Ltd., New York, NY, pp.259-294 (1994)
	AS	29	Gaich, G., et al., "Amino-Terminal Parathyroid Hormone-Related Protein: Specific Binding and Cytosolic Calcium Responses in Rat Insulinoma Cells," <i>Endocrinol.</i> 132:1402-1409, The Endocrine Society (1993)
	AT	29	Gardella, T.J., et al., "Converting Parathyroid Hormone-related Peptide (PTHrP) into a Potent PTH-2 Receptor Agonist," <i>J. Biol. Chem.</i> 271:19888-19893, The American Society for Biochemistry and Molecular Biology, Inc. (1996)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	30	Iida-Klein, A., et al., "Truncation of the Carboxyl-terminal Region of the Rat Parathyroid Hormone (PTH)/PTH-related Peptide Receptor Enhances PTH Stimulation of Adenylyl Cyclase but Not Phospholipase C," <i>J. Biol. Chem.</i> 270:8458-8465, The American Society for Biochemistry and Molecular Biology, Inc. (1995)
	AS	30	Iida-Klein, A., et al., "Structural Requirements of Parathyroid Hormone/Parathyroid Hormone-Related Peptide Receptors for Phospholipase C Activation and Regulation of Phosphate Uptake," <i>Miner. Electrolyte Metab.</i> 21:177-179, S. Karger AG (1995)
	AT	30	Inomata, N., et al., "Characterization of a Novel Parathyroid Hormone (PTH) Receptor with Specificity for the Carboxyl-Terminal Region of PTH-(1-84)," <i>Endocrinol.</i> 136:4732-4740, The Endocrine Society (1995)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

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	AR	<u>31</u>	Jing, S., et al., "GDNF-Induced Activation of the Ret Protein Tyrosine Kinase Is Mediated by GDNFR- α , a Novel Receptor for GDNF," Cell 85:1113-1124, Cell Press (1996)
	AS	<u>31</u>	Joun, H., et al., "Tissue-Specific Transcription Start Sites and Alternative Splicing of the Parathyroid Hormone (PTH)/PTH-Related Peptide (PTHrP) Receptor Gene: A New PTH/PTHrP Receptor Splice Variant that Lacks the Signal Peptide," Endocrinol. 138:1742-1749, The Endocrine Society (April 1997)
	AT	<u>31</u>	Karaplis, A.C., et al., "Lethal skeletal dysplasia from targeted disruption of the parathyroid hormone-related peptide gene," Genes & Devel. 8:277-289, Cold Spring Harbor Laboratory Press (1994)

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	APPLICANT Gardella et al.	
	FILING DATE October 17, 2001	GROUP 1645

U.S. PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	32	Kong, X.-F., et al., "The Rat, Mouse and Human Genes Encoding the Receptor for Parathyroid Hormone and Parathyroid Hormone-related Peptide are Highly Homologous," <i>Biochem. Biophys. Res. Comm.</i> 200:1290-1299, Academic Press (1994)
AS	32	Kovacs, C.S., et al., "Parathyroid hormone-related peptide (PTHrP) regulates fetal-placental calcium transport through a receptor distinct from the PTH/PTHrP receptor," <i>Proc. Natl. Acad. Sci. USA</i> 93:15233-15238, National Academy of Sciences (1996)
AT	32	Orloff, J.J., et al., "Analysis of PTHrP binding and signal transduction mechanisms in benign and malignant squamous cells," <i>Amer. J. Physiol.</i> 262:E599-E607, American Physiological Society (1992)

EXAMINER	DATE CONSIDERED
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	33	Orloff, J.J., et al., "A Midregion Parathyroid Hormone-Related Peptide Mobilizes Cytosolic Calcium and Stimulates Formation of Inositol Triphosphate in a Squamous Carcinoma Cell Line," <i>Endocrinol.</i> 137:5376-5385, The Endocrine Society (1996)
AS	33	Orloff, J.J., et al., "Further Evidence for a Novel Receptor for Amino-Terminal Parathyroid Hormone-Related Protein on Keratinocytes and Squamous Carcinoma Cell Lines," <i>Endocrinol.</i> 136:3016-3023, The Endocrine Society (1995)
AT	33	Potts, Jr., J.T., and Jüppner, H., "Parathyroid Hormone and Parathyroid Hormone-Related Peptide in Calcium Homeostasis, Bone Metabolism, and Bone Development: The Proteins, Their Genes, and Receptors," in <i>Metabolic Bone Disease</i> , 3 rd Edition, Avioli, L.V., and Krane, S.M., eds., Academic Press, San Diego, CA, pp. 51-94 (1998)

EXAMINER	DATE CONSIDERED
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>34</u>	Rubin, D.A., et al., "Molecular Cloning and Expression of Receptors for Parathyroid Hormone (PTH) and PTH-Related (PTHrP) Protein in Zebrafish," <i>Am. Zool.</i> 36:97A Abs No. 373, Society for Integrative and Comparative Biology (1996)
	AS	<u>34</u>	Rubin, D.A., and Jüppner, H., "Parathyroid Hormone (PTH)/PTH-Related (PTHrP) Receptor Cloning and In Situ Hybridization in the Zebrafish <i>Danio rerio</i> ," <i>Am. Zool.</i> 37:181A Abs. No. 651, Society for Integrative and Comparative Biology (1997)
	AT	<u>34</u>	Schipani, E., et al., "Identical Complementary Deoxyribonucleic Acids Encode a Human Renal and Bone Parathyroid Hormone (PTH)/PTH-Related Peptide Receptor," <i>Endocrinol.</i> 132:2157-2165, The Endocrine Society (1993)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	35	Schipani, E., et al., "Pseudohypoparathyroidism Type Ib Is not Caused by Mutations in the Coding Exons of the Human Parathyroid Hormone (PTH)/PTH-Related Peptide Receptor Gene," <i>J. Clin. Endocrinol. Metab.</i> 80:1611-1621, The Endocrine Society (1995)
AS	35	Sutcliffe, J.G., et al., "Antibodies That React with Predetermined Sites on Proteins," <i>Science</i> 219:660-666, American Association for the Advancement of Science (1983)
AT	35	Takasu, H., et al., "The 69-84 Amino Acid Region of the Parathyroid Hormone Molecule Is Essential for the Interaction of the Hormone with the Binding Sites with Carboxyl-Terminal Specificity," <i>Endocrinol.</i> 137:5537-5543, The Endocrine Society (1996)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>36</u>	Takasu, H. et al., "Human PTH/PTHrP receptors and Type-2 PTH Receptors Show Discordant Selectivity for Human PTH Analogs with Amino-Terminal Modifications," <i>Bone</i> 23:S255, Abstract No. T223, Elsevier Science (November 1998)
	AS	<u>36</u>	Treanor, J.J.S., et al., "Characterization of a multicomponent receptor for GDNF," <i>Nature</i> 382:80-83, Macmillan Journals Ltd. (1996)
	AT	<u>36</u>	Voet, D., and Voet, J.G., "A. Sickle-Cell Anemia: The Influence of Natural Selection," and "3. Abnormal Hemoglobins," in <i>Biochemistry</i> , Voet, D., and Voet, J.G., eds., John Wiley & Sons, Inc., New York, NY, pp. 126-128 and 228-234 (1990)

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	AR	<u>37</u>	Wu, T.L., et al., "Structural and Physiologic Characterization of the Mid-region Secretory Species of Parathyroid Hormone-related Protein," <i>J. Biol. Chem.</i> 271:24371-24381, The American Society for Biochemistry and Molecular Biology, Inc. (1996)
	AS	<u>37</u>	Yamamoto, S., et al., "Centrally Administered Parathyroid Hormone (PTH)-Related Protein (1-34) But Not PTH(1-34) Stimulates Arginine-Vasopressin Secretion and Its Messenger Ribonucleic Acid Expression in Supraoptic Nucleus of the Conscious Rats," <i>Endocrinol.</i> 138:383-388, The Endocrine Society (January 1998)
	AT	<u>37</u>	Yamamoto, S., et al., "Parathyroid Hormone-Related Peptide-(1-34) [PTHrP-(1-34)] Induces Vasopressin Release from the Rat Supraoptic Nucleus in Vitro through a Novel Receptor Distinct from a Type I or Type II PTH/PTHrP Receptor," <i>Endocrinol.</i> 138:2066-2072, The Endocrine Society (May 1997)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.